

SUPPORT FOR THE AMENDMENTS

Claims 6, 12, 18, and 24 have been canceled.

Claims 5, 7, 9, 11, 17, 19, 21, and 23 have been amended.

Claims 30-33 have been added.

The amendment to Claims 5, 7, 9, 11, 17, 19, 21, and 23 are supported by page 9, lines 20-24, page 11, lines 12-19, page 12, lines 12-15, page 13, lines 15-17, page 16, lines 7-8, page 16, lines 10-14, page 16, lines 18-22 and the Examples (see, for example, Example 1 at page 18, lines 12-18 and Example 4 on page 24). New Claims 30-33 are supported by page 16, lines 7-8.

The amendment to the specification at page 15 serves to correct a translation error.

Support for the amendment is provided by page 12, lines 12-15 of the original specification.

No new matter has been added by the present amendment.

REMARKS

Claims 1-5, 7-11, 13-17, 19-23, and 25-29 are pending in the present application.

The objections to (a) Claims 17-29 and (b) Claims 6 and 18, are obviated by amendment.

Claim 17 has been amended as suggested by the Examiner to insert “soy” after “unrefined”. Also, Claims 6 and 18 have been canceled.

Withdrawal of this ground of rejection is requested.

The rejection of Claims 5-29 under 35 U.S.C. §112, second paragraph, is obviated in part by amendment and traversed in part.

At the outset, Applicants wish to provide a concise explanation as to the following various terms that the Examiner appears to find problematic:

**Koji:** A mixture of raw materials such as soybean and koji molds such as *A. oryzae*

**Koji preparation step:** a step to keep koji generally at 22 to 40° C. for 24 to 72 hours. The purpose of the step is to make koji molds grow to increase enzymes such as proteases in koji molds. Even though proteins in the raw material are hydrolyzed to some degree but not sufficiently, the hydrolysis is not the main purpose of the step.

**Resulting koji:** Koji obtained after the koji preparation step is completed.

**Solid (resulting) koji:** Koji comprising a solid raw material and koji molds. Koji in soy sauce production as well as in the present invention is solid koji (cf. Liquid koji: a mixture where koji molds are inoculated with liquid culture medium).

**Unrefined soy** (“moromi” in Japanese): a mixture of the resulting (solid) koji and an aqueous solution (“charging water” in other word; saline in ordinary soy sauce process).

**Fermentation step:** Unrefined soy is kept at 5 to 45° C for 40 to 144 hours for sufficient hydrolysis.

Against this background, applicants will now address the series of indefiniteness rejections raised by the Examiner where allegations have been made that several of the terms in the original claims lack clarity, lack antecedent basis, or are relative terms. Below is a summary of these criticisms and Applicants corresponding comments:

- 1) Claims 5 and 17 are unclear for the following reasons:
  - a. What is “unrefined soy”?
  - b. How does “unrefined soy” differ from “resulting solid koji”?
  - c. Is soy the “raw material containing vegetable protein” or is it some other vegetable protein that is part of the “raw material”?
  - d. Is soy part of the “resulting solid koji” in step (i)?
  - e. Does the “solution” that is added to the solid koji “at a sodium chloride concentration of 5% by weight” comprise sodium chloride or is the sodium chloride already present in the solid koji and the solution is something else?
  - f. Does “a sodium chloride concentration of 5% by weight or less” pertain to the concentration of sodium chloride by weight of the solid koji or the solution or both or something else?

With respect to (a) and (b), Applicants again submit that the previously pending claims clearly indicated that the “unrefined soy” is the product of hydrolysis of the vegetable protein contained in the “resulting solid koji” prepared in step (i). This is clearly reflected in the explicit language of Claims 5 and 17. The Examiner makes no attempt to explain why this term is unclear or what the “something else” is that is referred to. Nonetheless, to expedite examination and to improve the clarity of the claims, Applicants have amended Claims 5 and 17 at step (i). One of the results of this amendment is that the phrase “the

resulting solid koji" has been replaced with "said solid koji". Thus, criticisms (a) and (b) are no longer believed to be applicable.

With respect to (c), Applicants submit that "soy" is not necessarily part of the "raw material", but rather is the product of step (ii), albeit in an unrefined form. Nonetheless, to improve the clarity of the claimed invention, Applicants have replaced the phrase "raw materials containing vegetable protein" with "composition comprising soybean protein". Thus, criticism (c) is no longer believed to be applicable.

Applicants respectfully submit that the indication in (d) is without merit as step (ii) clearly indicates that the "unrefined soy" is the product of hydrolyzing the vegetable protein from step (i).

With respect to (e) and (f), Applicants have rewritten step (ii) of Claims 5 and 17, based in part on page 9, lines 5-6 and page 15, lines 13-18, to specify that the sodium chloride concentration of 5% by weight or less refers to the concentration in the unrefined soy produced following hydrolysis and that the "sodium chloride concentration" referred to is based on the total weight of the unrefined soy.

- 2) The Examiner again alleges that the term "raw material" in Claims 5, 7, 8, 17, 19, and 20 is a relative term.

As stated above, to improve the clarity of the claimed invention, Applicants have replaced the phrase "raw materials containing vegetable protein" with "composition comprising soybean protein". Thus, this criticism is no longer believed to be applicable.

- 3) The Examiner continues to question whether the pH limitation (Claims 10 and 22) refer to the hydrolysis part of Claims 5 and 17, step (ii), or the fermentation part.

Applicants disagree and again submit that page 15, line 14 of the specification clearly states that raw materials, such as defatted soybean, are hydrolyzed during the fermentation

step. Therefore, the hydrolysis and fermentation occur during the same step and the time and temperature limitations refer to the conditions for fermentation.

Nonetheless, taking the various criticism in (1)-(3) above into consideration, Applicants have amended Claims 5 and 17 to improve the clarity of the claimed invention. Specifically, Claims 5 and 17 have been amended as follows:

A process of producing a seasoning comprising:

(i) preparing solid koji by inoculating one or more microorganisms ~~with protein hydrolysis potency in raw materials containing vegetable in a composition comprising soybean protein, wherein said microorganisms have protein hydrolysis potency and said microorganisms may be one or more belonging a genus selected from the group consisting of Lactococcus, Aspergillus, Rhizopus, Mucor, and Monascus~~; and

(ii) ~~hydrolyzing the protein forming unrefined soy by adding a solution to the resulting said solid koji, wherein the at a sodium chloride concentration of the unrefined soy is 5% by weight or less to form based on the total weight of said unrefined soy, purging the fermentation tank with nitrogen, sealing the fermentation tank, and then fermenting the unrefined soy by hydrolyzing the soybean protein at a temperature ranging from 30 to 37°C for 40 to 144 hours,~~

*[steps (iii) and (iv) in Claim 17 omitted]*

wherein a lactic acid bacterium is added ~~at the step (i)~~ at  $10^8$  to  $10^{11}$  cells per gram of ~~raw total~~ material ~~to the raw materials at the step (i)~~ and at the step (ii), a lactic acid bacterium is added ~~to the unrefined soy~~ at  $10^8$  to  $10^{11}$  cells per gram of unrefined soy ~~to the unrefined soy~~, and

wherein the seasoning is at a hydrolysis ratio to amino acids at 65% or more; an isobutyl alcohol concentration at 0.1 mg per gram of nitrogen or less; an n-butyl alcohol concentration at 0.25 mg per gram of nitrogen or less; an isoamyl alcohol concentration at 0.5 mg per gram of nitrogen or less; and an acetic acid concentration at 100 mg per gram of nitrogen or less.

In view of this amendment, Applicants submit that the foregoing criticisms are moot and should be withdrawn.

- 4) The Examiner alleges that Claims 11, 12, 23, and 24 are unclear for a number of reasons.

Applicants make no statement with respect to the propriety of this criticism and in no way acquiesce to the same. Nonetheless, to expedite examination of the claims only, Applicants have cancelled Claims 12 and 24 and have amended Claims 11 and 23 to require that step (ii) is conducted under a nitrogen atmosphere. Thus, this ground of criticism is now believed to be moot.

- 5) The Examiner alleges that the phrase “microorganisms with protein hydrolysis potency” is unclear as it is not certain whether the microorganisms added to koji have protein hydrolysis potency (i.e., proteases, etc.) or external enzymes having protein hydrolysis potency have been added to the koji in addition to the microorganisms.

Applicants respectfully submit that page 11, lines 12-19 define the meaning of this objected to phrase. “An applicant is entitled to be his or her own lexicographer and may rebut the presumption that claim terms are to be given their ordinary and customary meaning by clearly setting forth a definition of the term that is different from its ordinary and customary meaning(s).” MPEP §2111.01(IV).

Despite the foregoing, Applicants have amended the claims herein to define the microorganisms by as belonging to the genera Lactococcus, Aspergillus, Rhizopus, Mucor and/or Monascus. Thus, this ground of criticism is now believed to be moot.

In view of the foregoing, Applicants request withdrawal of this ground of rejection.

The rejections of: (a) Claims 5-7 and 9-16 under 35 U.S.C. §103(a) over Baensch in view of Takebe; (b) Claim 8 under 35 U.S.C. §103(a) over Baensch in view of Takebe and Arnaud; (c) Claims 11 and 12 under 35 U.S.C. §103(a) over Baensch in view of Takebe and Izumi; (d) Claims 17-19, 21-22, and 25-29 under 35 U.S.C. §103(a) over Baensch in view of Takebe and Marumoto; (e) Claim 20 under 35 U.S.C. §103(a) over Baensch in view of Takebe and Marumoto and further in view of Arnaud; and (f) Claims 23-24 under 35 U.S.C.

§103(a) over Baensch in view of Takebe and Marumoto and further in view of Izumi, are respectfully traversed.

In the Office Action mailed April 17, 2008, the Examiner has taken the position that the claimed invention is obvious over Baensch in view of Takebe, with or without Arnaud Izumi, and Marumoto. Applicants disagree and submit that the combination of Baensch and Takebe do not render the presently claimed invention obvious even when combined with Arnaud Izumi, and/or Marumoto.

Specifically, Applicants again submit that the disclosure of Baensch is deficient on several fronts, including:

- (a) failure to disclose addition of lactic acid bacteria during step (i) and (ii); (
- b) failure to disclose the concentration of the lactic acid bacteria present during either step (i) or (ii);
- (c) failure to disclose the hydrolysis ratio of the seasoning; and
- (d) failure to disclose the concentration of isobutyl alcohol, n-butyl alcohol, isoamyl alcohol, and/or acetic acid in the seasoning.

The Examiner alleges that Takebe compensates for (a) and (b), while (c) is inherent, and (d) would be expected “since [Baensch] teaches of similar process as instantly claimed”. Applicants disagree with the Examiner.

With respect to deficiency (a), Takebe does appear to provide some motivation to add lactic acid bacteria for both steps (i) and (ii), but such a suggestion merely provides a possible basis to perform the claimed method. Therefore, with respect to (a), even if the artisan were to combine the disclosure of Baensch with Takebe, the combination would provide and “invitation to experiment” or could be viewed as making it “obvious to try” to arrive at the present invention. However, “obvious to try” has long been held *not* to constitute

obviousness. *In re O'Farrell*, 7 USPQ2d 1673, 1680-81 (Fed. Cir. 1988). A general incentive does not make obvious a particular result, nor does the existence of techniques by which those efforts can be carried out. *In re Deuel*, 34 USPQ2d 1210, 1216 (Fed. Cir. 1995).

Some allege that *KSR* eliminates the “obvious to try” defense, but this is not the case. *KSR* clearly states that “obvious to try” may constitute obviousness, but only under certain circumstances. Specifically, *KSR* stated that the fact that a claimed combination of elements was “obvious to try” might show that such combination was obvious under 35 U.S.C. § 103, since, if there is design need or market pressure to solve problem, and there are finite number of identified, predictable solutions, person of ordinary skill in art has good reason to pursue known options within his or her technical grasp, and if this leads to anticipated success, it is likely product of ordinary skill and common sense, not innovation. However, the Examiner offers nothing to show how these factors apply and whether there would be such an expectation or anticipated success.

The fact of the matter remains, there must be some reasonable expectation of success. To this end, “the prior art can be modified or combined to reject claims as *prima facie* obvious as long as there is a reasonable expectation of success.” *In re Merck & Co., Inc.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). Before even addressing the issue of reasonable expectation of success it must be noted that the foregoing only addresses deficiency (a) in Baensch. At least three other deficiencies remain, which further cut against the obviousness of the claimed invention.

In regard to deficiency (b), the Examiner cites Takebe as compensating for this deficiency (i.e., disclosing the concentration of the lactic acid bacteria present during either step (i) or (ii)). However, the Examiner appears to recognize that Takebe disclose addition of an inoculum having significantly less bacteria than the claimed concentration. The Examiner

properly points out that Takebe disclose addition of an inoculum of  $10^3$  CFU per gram, which grows to  $1.2 \times 10^7$  CFU per gram during preparation of koji, and further grows to between  $2.2 \times 10^9$  to  $3.4 \times 10^9$  CFU per gram during hydrolysis.

Despite the Examiner's recognition of the failure of the combined disclosures of Baensch and Takebe to disclose the claimed concentrations, the Examiner alleges that the concentration differences and modification to arrive at the claimed concentrations "would not have involved undue experimentation on the part of one of ordinary skill in the art at the time of the invention." On this basis, the Examiner alleges that it would be obvious to modify the amount of lactic acid bacteria to arrive at the claimed values.

In the Office Action mailed April 17, 2008, the Examiner also alleges that the bacterial population grows during fermentation to fall within the claimed range. As such, the Examiner contends that the "effective bacterial population in the seasoning within the recited range of the applicant was known at the time of the invention. Therefore, it would have been well within the purview of one of ordinary skill in the art to

- either add more bacteria to the culture medium and maintain the bacterial population or
- to add a rapidly multiplying bacterial strain and provide conditions for rapid increase in the population of bacteria in the vegetable protein culture medium based on the strain of bacteria, availability and cost constraints at the time."

Applicant submit that this allegation is misplaced on its own. It must be noted that the artisan is not simply making a close step or modification to arrive at the claimed invention. The fact remains that the Examiner would first need to modify the disclosure of Baensch based on the disclosure of Takebe to allegedly arrive at addition of lactic acid bacteria for both steps (i) and (ii). Subsequently, the artisan would need to then modify the

combined disclosures of Baensch and Takebe to increase the concentration of lactic acid bacteria by *orders* of magnitude to arrive at the claimed invention. Clearly this is beyond routine experimentation or obvious optimization.

Moreover, this allegation by the Examiner is unsupported and would only be apparent if the skilled artisan had the benefit of Applicants' disclosure and hindsight analysis based thereon.

Moreover, it is also notable that Baensch and Takebe fail to disclose the hydrolysis ratio of the seasoning (deficiency (c)) and the concentrations of isobutyl alcohol, n-butyl alcohol, isoamyl alcohol, and/or acetic acid in the seasoning (deficiency (d)).

With respect to the hydrolysis ratio, the Examiner cites Wiley p. 2178. However, this reference does not appear to support the Examiner's conclusion.

On page 11, lines 1-3 of the specification the term "hydrolysis ratio to amino acids" is defined as the "ratio of *free amino acids* to the total amount of amino acids contained in the hydrolyzed solution." Wiley disclose that the use of defatted soybean instead of whole beans increases the "protein digestibility of raw materials from 65 to 95%". This disclosure by Wiley does not state what amount of the digested raw materials is "free amino acids". Further, lines 4-5 under the heading "Composition" in Wiley clearly indicate that lower peptides and peptones are present in addition to amino acids. This is important as "[t]he fact that a certain result or characteristic may occur or be present in the prior art is not sufficient to establish the inherency of that result or characteristic. *In re Rijckaert*, 9 F.3d 1531, 1534, 28 USPQ2d 1955, 1957 (Fed. Cir. 1993); *In re Oelrich*, 666 F.2d 578, 581-82, 212 USPQ 323, 326 (CCPA 1981). "In relying upon the theory of inherency, the examiner must provide a basis in fact and/or technical reasoning to reasonably support the determination that the allegedly inherent characteristic necessarily flows from the teachings of the applied prior art."

*Ex parte Levy*, 17 USPQ2d 1461, 1464 (Bd. Pat. App. & Inter. 1990) In this case, the Examiner has clearly failed to meet this burden.

With respect to deficiency (d), the Examiner's position is based on the "similarity" between the claimed method and the method disclosed by Baensch. However, for the reasons given above, Applicants submit that the claimed method and the method disclosed by Baensch are not "similar", but rather differ on several important fronts. Therefore, it is not reasonable to conclude that the concentrations of isobutyl alcohol, n-butyl alcohol, isoamyl alcohol, and/or acetic acid in the seasoning would be achieved by the method disclosed by Baensch.

Applicants further submit that Baensch, as well as the present invention, is related to a seasoning obtained by protein hydrolysis where a hydrolysis ratio to amino acids needs to be higher. However, Takebe is not related to a seasoning at all. In Takebe, the content of aglycones of isoflavone compounds is important and a hydrolysis ratio to amino acids is not. Therefore, a skilled artisan would have not motivation and/or reason to combine the disclosures of Baensch and Takebe as the Examiner has done.

An additional key difference between the present invention and the combination of Baensch and Takebe is the temperature and the period of time at the fermentation step.

Present Invention	Baensch's	Takebe's
35°C, 48-144 hrs in Example 1	10°C, 14 days in Examples 1-4	30°C, 24 hrs at col. 11, line 30
30-37°C, 96 hrs in Example 2		(Table 4)
35°C, 96 hrs in Examples 3-4		50°C, 48 hrs at col. 12, line 9 (Table 5)

As described in Baensch at column 2, lines 11-17, undesirable microorganisms grow when hydrolysis is operated under salt free or low salt (<5%) condition. As such, the fermentation in Baensch had to be operated at low temperature like 10°C for avoiding spoilage by the undesirable microorganisms and for longer period of time like 14 days for sufficient hydrolysis. On the other hand, the fermentation period of time is shorter in the present invention since the temperature is higher and the fermentation is operated in a sealed tank purged with nitrogen as described in Example 3. Needless to say, the shorter fermentation is very advantageous in the light of production efficiency.

Takebe does not disclose a method to produce a seasoning and is not related to the present invention. Further, the skilled artisan would appreciate that Takebe's fermentation condition at 30°C for 24 hrs is not sufficient to hydrolyze proteins for a seasoning. In addition, the skilled artisan would appreciate that Takebe's other condition at 50°C for 48 hrs is not suitable for a seasoning since an undesired burned flavor in the seasoning is produced. Thus, the combined disclosures of Baensch and Takebe falls short yet again.

Arnaud is cited as disclosing that "extrusion cooking of defatted soy was known in the art at the time of the invention". And, Izumi is cited as disclosing "a method of making soy based seasoning where the fermentation of soy sauce takes place in large batches in a closed type tank in order to reduce the fermentation time of the soy based seasoning." Marumoto is cited for disclosure of sterilization. Although reserving the right to do so later, Applicants make no statement with respect to the propriety of these assertions by the Examiner and make no statement as to the propriety of combining Arnaud, Izumi, and/or Marumoto with Baensch and Takebe. However, Applicants do take this opportunity to note that even if the disclosures of Arnaud, Izumi, and/or Marumoto are combined with Baensch and Takebe, the

aforementioned deficiencies in the combined disclosures of Baensch and Takebe are not remedied.

Accordingly, for the reasons given above, withdrawal of these grounds of rejection is requested.

Applicants submit that the present application is now in condition for allowance. Early notice to this effect is earnestly solicited.

Respectfully submitted,

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